

withdrawn from consideration, without prejudice. Claims 1-15 are currently examined on the merits.

REMARKS

In view of the remarks set forth below, Applicants traverse the outstanding rejections and respectfully request reconsideration of the rejection of the claims as cited in the May 3, 2002 Office Action.

Applicants gratefully acknowledge withdrawal of the rejection under 35 U.S.C. § 102 of claims 8-10 in view of the February 7, 2002 Amendment.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 1-7 and 11-15 stand rejected under 35 U.S.C. § 102(b) as anticipated by Paul *et al.* (US 5,292,538; "the '538 patent"). According to the Examiner, Paul *et al.* discloses a nutritional composition comprising glucose polymers, lactalbumin (whey protein), **amino acid ligands** (e.g. zinc arginate), potassium, phosphorus, alpha-ketoglutarate (within the claimed range), lipoic acid (within the claimed range), vitamin C and inositol.

It is axiomatic that in order for a claim to be anticipated under 35 U.S.C. § 102(b), a single prior art reference must disclose each and every element of the claim. (See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986) ("for prior art to anticipate under § 102 it has to meet every element of the claimed invention"), cert.denied, 480 U.S. 947, 107 S.Ct. 1606 (1987). It is respectfully submitted that the '538 patent does not meet this legal standard because it does not disclose each and every element of independent claim 1.

Independent claim 1 is directed to a food supplement comprising alpha-lipoic acid or a derivative thereof, and at least one ingredient selected from the group consisting of **amino acids and derivatives** thereof and **sources of amino acids**, in amounts effective to increase lean muscle mass and strength.

The examiner correctly stated that the '538 patent discloses a nutritional composition comprising. . . , **amino acid ligands** (e.g., zinc arginate). . . . But the examiner's reliance on the "amino acid ligands" disclosed in the '538 patents as same ingredient as recited in the independent claim 1 of the present invention (namely: **amino acid and derivatives** therefor as well as **sources of amino acid**) is misplaced.

The '835 patent specification defines the "amino acid ligand" as a complex between a natural occurring amino acid and a metal ion in a certain stoichiometric relationship and characterized the complex as a covalent compound with unique properties of bioavailability. Specifically, the '835 specification states :

"Bioavailable forms of magnesium, potassium, and other minerals, such as manganese, zinc, iron, boron, copper, molybdenum, and chromium, which are utilized in facilitating and sustaining endurance and anabolism, are made by chelating or complexing the mineral with an amino acid or peptide. The ligand to mineral ratio in these chelates is at least 1:1 and, except for potassium, is preferably, 2:1 or higher. The molecular weight of these amino acid chelates is not greater than **1,500 daltons** and preferably does not exceed 1,000 daltons. Such amino acid chelates are **stable** and are generally taught in the prior art to be **absorbed intact through the intestinal tract via an active dipeptide transport**... Such amino acid chelates have a stability constant of between about 10^6 and 10^{16} ..." (col. 5, lines 5-23).

"... amino acid chelate - a metal ion from a soluble salt with amino acids with a mole ratio of one mole of metal to one to three (preferably two) moles of amino acids to form coordinate **covalent bonds** It is also no well documented that amino acid chelates can be prepared from metal ions which do not come from soluble salts" (col. 5, lines 40-60).

"As referenced above, various studies have found that minerals in the forms of amino acid chelates, composed of amino acid ligands or combinations of amino acid and vitamin acid ligands (e.g. glycinate, arginate, and nicotinate glycinate) **render the minerals more readily absorbable** . . ." (col. 5, lines 61-66) (emphasis added).

The '835 patent also points to U.S. Pat. Nos. 4,599,152 ("the '152 patent") and 4,863,898 ("the '898 patent") which further characterizes "amino acid chelates." The structural formula of an amino acid chelate as depicted in both the '152 and '898 patents is not the same as that of the structural formula of an amino acid or its derivatives. Specifically, the '898 patent distinguishes naturally occurring amino acids

from the amino acid chelates:

"By amino acid chelates is meant the product resulting from the reaction of a polypeptide, dipeptide or naturally occurring alpha amino acid with a metal ion having a valence of two or more to form a ring structure wherein the positive electrical charges of the metal ion are neutralized by the electrons available through the carboxylate or free amino groups of the alpha amino acid . . ." (col. 1, lines 21-28).

The '898 patent exemplifies naturally alpha amino acid as alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutaminc acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine or dipeptides, tripeptides or quadrapeptides formed by any combination of the above. Each chelated metal ion will contain at least two ligands forming two heterocyclic rings but may, in certain instances, contain up to four ligands forming at least tow or four heterocyclic rings depending upon the coordination number of the ion (col. 5, lines 19-31).

A prior art reference must "clearly and unequivocally disclose the claimed invention . . ." In re Arkley, 455 F.2d 586, 587 (CCPA 1972). The reference must therefore provide a certain degree of precision with respect to the specific compound claimed. For example, in Ex parte Westphal, 223 USPD 630 (Bd. Pat. App. 1983, the claim was directed to a composition containing 3-methylthio-4-amino-6-tert-butyl-1,2,4-triazine-5-one. The examiner rejected the claim under section 102 as anticipated by, *inter alia*, a patent to Fawzi. The Fawzi patent disclosed a compound substituted at a particular position with alkyl having 1 to 8 carbon atoms, but did not specifically name the claimed tert-butyl radical. The Board found that the Fawzi patent did not provide the precision necessary for anticipation under section 102. *Id.* at 631. The court further found that there was nothing in the reference that "clearly and unequivocally" directs those in the art to make this selection *Id.* at 526.

Here, the '835 patent merely discloses "amino acid ligands", but does not teach the use of amino acids or sources of amino acids. The '835 patent explicitly states the significant differences between an amino acid and an amino acid ligand. The disclosure of "amino acid ligands" in the '835 patent fails to provide a certain degree of

precision with respect to the specific compound claimed in the present application. There is nothing in the '835 patent that "clearly and unequivocally" directs those in the art to make a selection to choose the specific ingredients of the present invention.

For at least these reasons, it is respectfully submitted that the '538 patent cannot anticipate independent claim 1, or claims 2-7 and 11-15, which depend from and further limit claim 1.

Additionally, applicants respectfully further maintain the arguments that are submitted in the February 7, 2002 Amendment. In short, applicants maintain that the '538 patent merely teaches: i) lipoic acid as an **optional** antioxidant and actually teaches that the nutritional composition works in anabolic physiology even **in the absence of** lipoic acid; ii) a **relatively smaller** amount of lipoic acid (i.e., 64.1-88.0 ug) (col. 9-10, Table); and iii) a food formulation that **must** contain magnesium.

Based on the foregoing reasons, Applicants respectfully urge the Examiner to withdraw the 35 U.S.C. § 102(b) rejection.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as anticipated by Paul *et al.* (US 5,292,538; "the '538 patent") in view of Riley (US 5,976,568, "the '568 patent"). According to the Examiner, the '538 patent discloses a nutritional composition comprising glucose polymers, lactalbumin (whey protein), **amino acid ligands** (e.g. zinc arginate), potassium, phosphorus, alpha-ketoglutarate (within the claimed range), lipoic acid (within the claimed range), vitamin C and inositol. The examiner acknowledges that the '538 patent does not teach the exact amount of lipoic acid claimed herein. The examiner alleges that the '568 patent teaches a nutritional supplement comprising from about 0.0 mg to about 750 mg of alpha lipoic acid (claim 1, col. 29). The examiner further alleges that one skilled in the art would have been motivated to optimize the amount of alpha lipoic acid.

As reasoned above, Applicants respectfully submit that the '538 patent fails to

disclose "amino acid and derivatives thereof as well as sources of amino acid" as recited in the independent claim 1 of the present invention. This defect cannot be cured by the '568 patent. Finally, the '538 patent does not provide any motivation to one skilled in the art to combine the teachings of the '538 patent with those of '568 patent. As such, the examiner fails to establish a *prima facie* obviousness case.

Based on the foregoing reasons, Applicants respectfully urge the Examiner to withdraw the 35 U.S.C. §103(a) rejection.

CONCLUSION

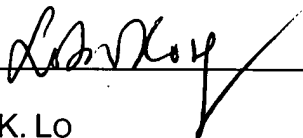
In view of the foregoing, Applicant respectfully submits that all the pending claims are in condition of allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at (212) 908-6018.

The Commissioner is authorized to charge any required fees which may be due to Deposit Account No. 11-0600.

RESPECTFULLY SUBMITTED
KENYON & KENYON

DATED: OCTOBER 8, 2002

BY: _____


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